Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13408

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13408

Center for Food Safety and Applied Nutrition
Food and Drug Administration

Memo

To: SN/AEMS Adverse Event Monitor

From: Lori A. Love, M.D., Ph.D.
Director, Clinical Research and Review Staff
Office of Special Nutritionals

CC: file

Date: 03/15/99

Re: Adverse event with an ephedrine alkaloid-containing product

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The following is a summary of a telephone discussion with Ms [redacted] on March 12, 1999. Ms [redacted] had originally called MedWatch, who took a message and forwarded the information to me. Ms [redacted] had called to report on her husband who was essentially in a coma following repeated seizures that the family believes is associated with his use of the product, Ripped Fuel.

Mr. [redacted] is a 26 year old who had used the product Ripped Fuel on and off for approximately the past 3 years. His wife stated that he had been somewhat stressed and tired, and had complained of a headache for 3 days before the event. He experienced his first seizure on February 20, 1999, after he had taken Ripped Fuel at 2:00 p.m. Over the next few days, he had repeated seizures for which medical care was sought. He was hospitalized in the ICU of [redacted] with repeated recurrent seizures which they have attempted to treat by inducing a pentobarbital coma. He remains in the hospital in a very guarded condition according to his wife.

Ms. [redacted] has agreed to permit FDA to obtain additional information about her husband's case, including a written affidavit, a copy of the product label/labeling [the actual product is no longer available] and her husband's medical records. Her husband's doctor is Dr. [redacted] (at [redacted] [redacted] Ms. [redacted] is currently staying at her father-in-law home in [redacted] [details below]. Please initiate an expedited follow-up on this case.

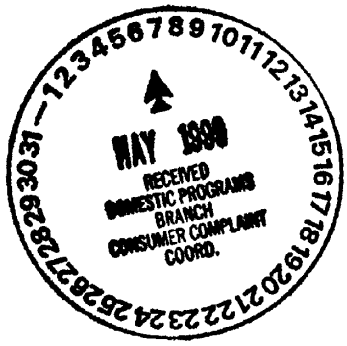
[redacted]

 [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751



Date: April 5, 1999

From: Investigator, [redacted]

To: Supervisory Investigator, HFR-SE2585

Subject: **Adverse Event Report**
[redacted] **CFSAN Project #13408**
Re: Ripped Fuel Supplement
[redacted]

The subject assignment dated 3/19/99 was issued from CFSAN, Domestic Programs Branch, HFS-636. This assignment requested a follow-up investigation be conducted. The assignment recorded an Adverse Event Report concerning a consumer's reaction after ingestion of an ephedra alkaloid-containing product. The assignment requested the collection of medical records, product labeling and information to complete the Adverse Event Questionnaire form. The Adverse Event Questionnaire form, FDA-2516 form, and the documentary sample, DOC 46060, were submitted to HFS-636 on 4/12/99.

INVESTIGATION

Mrs[redacted] initiated called Medwatch to report her husband serious reaction believed to be caused by his use of the product Ripped Fuel. On 3/29/99 and 4/3/99, I interviewed Mrs.[redacted] at her husband's parents' home at [redacted] Mrs.[redacted] has been staying at this home since her husband's hospitalization (2/21/99). I asked Mrs.[redacted] o provide some background information and to review the events surrounding her husband's illness. Mrs.[redacted]

To: ARMS Monitor, DOEP, HFS-636

This memorandum records the initial interviews with the [redacted] family and provides the medical records collected from two of the hospitals. Receipt of additional medical records from a third hospital and additional interviews with medical personnel are pending.

Leon L. Law
Supervisory Investigator
[redacted]

Cc: FLA-DO
[redacted]

[redacted] and Mr. [redacted] s mother and stepfather, were present during the 3/29/99 interview. They provided information where noted. The following information was provided:

[redacted] husband is Mr. [redacted] twenty-six years old (DOB [redacted] They have been married for two and half years and have an infant daughter. They reside at [redacted] Mr. [redacted] is a physically fit, young man with no history of illness or serious injury. He has no known allergies and was not on any prescription medications prior to the event. His family does not have any history of illness or seizure activity. [redacted] has been employed at [redacted] since late 1996 and has worked at three area locations. He started his employment as a waiter. He has worked as the [redacted] Assistant Manager at the [redacted] since 1/24/99. He typically works 60-70 hours per week.

[redacted] has been using the product Ripped Fuel for an estimated three years. [redacted] showed me an itemized receipt dated 1/29/96 from [redacted] in [redacted] including the purchase of two bottles of Ripped Fuel. Mrs. [redacted] did not know how often her husband took the product. She could not state he took the product every day. She stated he took two-three capsules at a time. She could not provide any average of how many were taken per week, or month. [redacted] [redacted] or Mrs. [redacted] mother) normally purchased the product. [redacted] could not estimate product usage based on product purchases. She did know that he generally took the capsules for extra energy when exercising (mountain biking) or while at work. [redacted] is not a body builder and did not have a special workout routine. He is not a drinker or smoker. For three days prior to the incident (2/18-20/99), [redacted] complained of a slight headache. He took 1-2 tablets of Tylenol as needed for the headache. On 2/20/99, [redacted] arrived at work prior to 4pm. He had eaten lunch with his wife during the day. At approximately 7pm, he took two Ripped Fuel capsules with a soft drink. He consumed some additional glasses of the soft drink throughout the evening. No other food was consumed. Around 9:00pm, [redacted] was talking with his wife on the phone. [redacted] stated he started to sound disoriented. He then no longer was available on the line. She later learned [redacted] had experienced a seizure.

[redacted] was taken via ambulance from [redacted] to [redacted] Emergency Room Department. According to the medical records from [redacted] (**Attachment #1**), [redacted] experienced a grand mal seizure while in the emergency room. He was given Ativan 2 mg IV. Urine and blood drug screens were negative. The CBC test report showed a low potassium level. [redacted] was given KCL. The [redacted] emergency room report listed that his initial glucose level was in the 40's. He was also given one amp of D50 to raise his blood sugar. The emergency room report recorded the differential diagnosis as hypoglycemia seizure disorder with metabolic abnormality. It was reported on the handwritten emergency room notes and the typed report that [redacted] was taking a natural energy booster/ripped fuel (written as Ripflu). He was observed for three additional hours without any seizure

activity. He ate a meal and his condition was listed as stable. [redacted] was discharged from [redacted] at 4am on 2/21/99. [redacted] stayed at his parent's home on 2/21/99. [redacted] stated that [redacted] was tired and nauseated from the medications on 2/21/99.

In the afternoon of 2/21/99, [redacted] went out to the store. Around 5:30pm, [redacted] again experienced a seizure. Mrs. [redacted] called the paramedics. [redacted] arrived at the house while [redacted] was having the seizure. He was taken via ambulance to [redacted] Copies of the [redacted] medical records were collected as **Attachments #2-6**. [redacted] had another seizure in the emergency room. The ER notes and triage reports, **Attachment #2**, include a notation of the Ripped Fuel labeled ingredients. He was admitted to the hospital's Progressive Care Unit. The History & Physical and Consultation reports are provided as **Attachment #3**. These documents also comment on Mr. [redacted] taking over the counter extracts and Ripped Fuel. [redacted] stated that her husband continued to experience seizures at [redacted] She stated that the seizures would increase in frequency and duration. Copies of all progress notes provided are attached as **Attachment #4**. Physician Orders are attached as **Attachment #5**. All provided tests reports are attached as **Attachment #6.** [redacted] condition worsened. He was intubated and moved to ICU. The family requested that he be transferred to [redacted]

[redacted] was transferred to [redacted] on 2/25/99. [redacted] stated that [redacted] medical staff decided to treat his condition by drug inducing a coma. This treatment plan was followed until around 3/11/99. [redacted] was experiencing side effects from the drug induced coma. [redacted] remains on antiseizure medications. He was moved from ICU to the [redacted] Progressive Care Unit on 3/28/99.

Copies of [redacted] medical records were not readily available. The Medical Records Department initially declined in writing the FDA request for copies due to the fact that the patient had not yet been discharged. A second request was made on 4/12/99. The copies will be provided to FDA. Those medical records will be submitted with a separate memorandum. Recent attempts to schedule an interview with the attending neurologist and an internal medicine specialist have been unsuccessful.

During the 3/29/99 interview, Mr. [redacted] provided a photocopy of a prescription note (**Attachment #7**) identified as written by [redacted] M.D., Neurologist. Dr [redacted] is one of the attending neurologists at [redacted] treating [redacted] The handwritten note records that [redacted] is severely brain damaged as a result of his ingestion of Ma Huang, Ripped Fuel. Mr. [redacted] stated that additional medical personnel also suspected the supplement product as the causative factor. The [redacted] family may pursue legal action. The investigation is ongoing.

Attachments

1. [redacted] medical records
2. [redacted] emergency room records
3. [redacted] Consultation reports
4. [redacted] Progress Notes
5. [redacted] Physician Orders
6. [redacted] Test reports
7. [redacted] Prescription Note

Shari J. Hromyak
Investigator
[redacted]

UNITED STATES FOOD AND DRUG ADMINISTRATION

CONSUMER COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: FLA-9339

2. DATE OF COMPLAINT: 3/29/99

3. FORM OF COMPLAINT
(1) ☒ TELEPHONE (4) ☐ OTHER
(2) ☐ LETTER
(3) ☒ VISIT

4. SOURCE OF COMPLAINT
☒ CONSUMER ☐ TRADE SOURCE
☐ GOVERNMENT ☐ OTHER
☐ LOCAL ☐ STATE ☐ FEDERAL

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS: [redacted]
b. TELEPHONE NUMBER
HOME [redacted]
WORK: N/A

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY

FLA-DO received an investigation request from CFSAN/HFS-636 dated 3/19/99. That assignment recorded that the complainant originally called MedWatch. On 3/12/99, the Office of Special Nutrionals staff spoke with Mrs. [redacted] She reported that her husband experienced recurrent violent seizures after his ingestion of a dietary supplement, Ripped Fuel. Mr. [redacted] remains hospitalized. Medical staff attempted to treated his seizures by drug inducing a coma. The family and at least one neurologist directly attribute that Mr [redacted] seizures were caused by his use of the Ripped Fuel. The current prognosis is permanent mental impairment.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? ☐ NO ☒ YES *(If Yes, explain in Remarks)*

7. INJURY OR ILLNESS RESULTED
(1) ☐ NO
(2) ☒ YES
(If "yes" complete items a through d)

a. DEIO/EMOPS *(HFC-130)* NOTIFIED
(1) ☐ NO
(2) ☒ YES
DATE 4/9/99--sent 2516

b. TYPE SYMPTOM — ONSET (HR.)
(1) ☐ VOMITING
(2) ☐ NAUSEA
(3) ☐ DIARRHEA
(4) ☐ FEVER
(5) ☐ SKIN/EYE IRR.
(6) ☒ HEADACHE — three days
(7) ☒ OTHER seizures — two hours

c. ATTENDING HEALTH PROFESSIONAL
(1) ☐ NO (2) ☒ YES
(If "yes, give name, address, phone)
[redacted]

d. HOSPITALIZATION REQUIRED
(1) ☐ NO (2) ☒ YES
(If "yes", give name, address, phone, date)
[redacted]

8. PRODUCT AND LABELING
a. BRAND NAME: TWINLAB
b. PRODUCT NAME: RIPPED FUEL, THERMOGENIC FORMULA
c. SIZE AND PACKAGE TYPE: 100 CAPSULES, GLASS BOTTLE
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e. LOT/SERIAL NUMBER: unknown
EXP/USE BY DATE: n/a
f. DATE PURCHASED: 1/20/99
g. PRODUCT USED (1) ☐ NO (2) ☒ YES
DATE 2/20/99
h. AMT REMAINING: 0-discarded by wife

9. MANUFACTURER/ DISTIBUTOR OF PRODUCT
a. HOME DISTRICT: NYK
b. CFN: 2421049
c. NAME AND LOCATION OF FIRM:
TWIN LABORATORIES INC
2120 Smithtown Avenue
Ronkonkoma, NY 11779
d IMPORT PRODUCT
(1) ☒ NO
(2) ☐ YES

10. EVAULATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX
(2) DESCRIPTION: seizures
b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE
c DISPOSITION
(1) ☒ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT EI
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY
(5) ☐ REFERRED TO STATE/ LOCAL AGENCY
(6) ☐ REFERRED TO OTHER FDA DISTRICT
(7) ☐ REFERRED TO OCI
11 PRODUCT CODE: 54FCE09
12 INFORMATION COPIES TO
☐ HFC-130 ☐ HFD-730
☐ HFM-650 ☐ HFS-635
☐ HFV-210 ☐ HFZ-530
☒ OTHER HFS636

REMARKS
Investigation is ongoing. Complainant will be contacted for additional information and clarification pending receipt of [redacted] medical records.

NAME AND TITLE: Shari J. Hromyak, CSO

DATE: 4/9/1999

FORM FDA 2516 (5/11/98)

000006

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: FLA-9339

2.a. ACTION REQUESTED
(1) [X] INVESTIGATION
(2) [X] COLLECT SAMPLE
(3) [ ] INSPECTION
(4) [ ] OTHER:

2.b. REMARKS (Additional details)
Collect Med Records, fill out Adverse Event Questionnaire + collect labeling

2.c. REQUESTING OFFICIAL'S NAME AND TITLE: CFSAN / HFS-636

2.d. DATE REQUESTED: 3/19/99

2.e. PRODUCT NAME: Ruptel Fuel

3.a. ASSIGNED TO: LLC / SJH

3.b. DUE BY: 3/29/99

4.a. ACTION TAKEN
(1) [X] INVESTIGATION
(2) [X] SAMPLE COLLECTED
(3) [ ] INSPECTION
(4) [ ] NONE

4.b. SAMPLE NUMBER(s): POC 460460

4.c. DESCRIPTION OF ACTION TAKEN
See Memos of Investigation dated 4/5/99 and 4/13/99.

4.d. ACTION OFFICIAL'S NAME AND TITLE: Shari J. Hromyak CSO

4.e. ACTION DISTRICT: FLA

4.f. DATE COMPLETED: 4/ /97

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

5.a. HOME DIST.: NYK

5.b. CF NO.: 2421049

5.c. NAME AND ADDRESS: TWIN LABORATORIES INC 2120 Smithtown Ave Ronkonkoma, NY

6. PROGRAM DATA

6.a. OPERATION: 13

6.b. PAC: 09R801

6.c. PRODUCT CODE: 54FCE09

6.d EMP. HOME DIST.: FLA

6.e. EMP. NO.: 215

6.f. POS CL.: 2

6.g. HOURS: 14 1/2

7. EVALUATION
(0) [ ] PENDING
(1) [ ] NO ACTION INDICATED (NAI)
(2) [ ] VOLUNTARY ACTION INDICATED (VAI)
(3) [ ] OFFICIAL ACTION INDICATED (OAI)
(4) [ ] NOT AN FDA OBLIGATION
(5) [ ] REFERRED TO HOME DISTRICT
(6) [ ] INSUFFICIENT INFO. UNABLE TO EVAL.
(7) [ ] REFERRED TO OCI

8. FINAL DISPOSITION
(1) [ ] FOLLOW-UP NEXT E1
(2) [ ] WARNING LETTER
(3) [ ] CITATION
(4) [ ] SEIZURE
(5) [ ] INJUNCTION / PROSECUTION
(6) [ ] REFERRED TO OTHER AGENCY
(Indicate Agency in **Remarks***)*
(7) [ ] RECALL
(8) [ ] NO ACTION

9. INFO. COPIES TO:
[ ] HFB-100
[ ] HFD-730
[ ] HFV-236
[ ] HFZ-343
[ ] HFC-161
[X] HFS-635
[X] NYK-DO
[ ] _____
[ ] _____
[ ] _____
[ ] _____
[ ] _____
[ ] _____

REMARKS
Referred to HFS-635

000007

NAME AND TITLE OF DISPOSITION OFFICIAL: Leonard Lamm

DISPOSITION: FLA-DO

DISPOSITION DATE: 5/7/99

FORM FDA 2516a (3/94)

★ U.S GPO: 1995-386-960/20706

CFSAN

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

ARMS 13408

Form Approved: OMB No. 0910-0291 Expires: [illegible]
See OMB statement on re[illegible]

FDA Use Only 100214

Triage unit sequence # 99176

13433

Page 2 of 2 RIPPED FUEL

A. Patient information

1. Patient identifier	2. Age at time of event	3. Sex	4. Weight
MALE	26	☐ female ☑ male	___ lbs or 86 kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event: 2/20/99

4. Date of this report: 3/8/99

5. Describe event or problem

26 YO M TOOK RIPPED FUEL BY TWIN LABS A DIET SUPPLEMENT FOR ATLEAST A YEAR UNTIL OFF. TOOK SEVERAL DOSES & THEN HAD A SEIZURE WAS HOSPITALIZED & CONTINUED TO HAVE SEIZURE EPISODES → STATUS EPILEPTICUS. WAS PLACED ON PENTOBARBITAL COMA TO CONTROL SEIZURES. CONTINUED TO HAVE BREAKTHROUGH SEIZURES WHILE ON PENTOBARB. DIFFICULT TO WEAN OFF. ADMITTED TO NEUROTECH FOR CARE.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM
HF-2

MAR 9'99 - 7:49

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
- #1 MA-HUANG EXTRACT - 334mg, EPHEDRINE 10[illegible]
- #2 GUARANA EXTRACT - 910mg, CHROMIUM PICOLI[illegible]

2. Dose, frequency & route used
- #1 SEVERAL CAPSULES
- #2 DAILY

3. Therapy dates (if unknown, give duration)
- #1 CHRONIC >1 YEAR 20[illegible]
- #2

4. Diagnosis for use (indication)
- #1 METABOLIC ENHANCER
- #2 DIET SUPPLEMENT

5. Event abated after use stopped or dose reduced
- #1 ☐ yes ☐ no ☐ does not apply
- #2 ☐ yes ☐ no ☐ does not apply

6. Lot # (if known)
- #1
- #2 TWIN LABS

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☐ does not apply
- #2 ☐ yes ☐ no ☐ does not apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

MAR 1999
RECEIVED
BRANCH
CONSUMER COMPLAINT
COORD.

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

BEC'D.

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date

6.
- model #
- catalog # MAR 12 1999
- serial #
- lot # MEDWATCH CTU
- other #

7. If implanted, give date

8. If explanted, give date

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address [redacted]

Phone #

2. Health professional?
☑ yes ☐ no

3. Occupation: PHARMACIST

4. Also reported to:
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

000008

CTC 99176

Adverse Reaction Information Form A

Complaint Number: FLA-9339 Investigator: SJH/215

Consumer Information

Date of Report: 03/12/99 (MM/DD/YY)
Date of Visit: 03/29/99

Initial Report Source: ☒FORA Consumer Injury
☒Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☐F ☒M Age: 26 DOB: [redacted]

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 2/20/99
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): at work - [redacted]

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
Mr. [redacted] experienced seizures - generalized tonic/clonic
How long did the symptoms last? seizure - two - four minutes symptoms - 30-45 min
Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.).
2 capsules taken w/ soft drink @ 7pm. frequency unknown
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
No food, meds or other supplements
Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☒No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No see memo - patient seen at three hospitals
Give health care provider's name, address and telephone number:
ER - [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☒Other (specify) Emergency Room Staff

What medical tests were performed and what were the results?
CBC, EKG, Tox blood + urine drug screen
What was the medical diagnosis? seizure disorder
What treatment(s) was given (e.g., drugs, other)?
one amp D50, 40 meq KCL, Ativan 2mg IV

Were there any preexisting condition(s)/treatment(s)? None
(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No N/A

Product Category

1. Adverse reaction to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object (specify): _____

3. ☐Other (specify): _____

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Information on Suspected/Alleged Product

Give the product name (including dose/serving size, duration of use, and reason for taking):
Ripped Fuel TWINLAB Metabolic Enhancer
60 Capsules, Up to 2 capsules 3 x/day
Maximum dose of ephedra 100 mg in 24 hours for NOT MORE THAN 12 weeks

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown

TWO CAPSULES PROVIDE:

Ma Huang Extract	334 mg (20 mg ephedra)
Guarana Extract	910 mg (22% caffeine)
L-Carnitine	100 mg
Chromium	200 mcg (chromium picolinate)

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐Aspartame ☐Color Additive (please specify) _____
☐Monosodium Glutamate
☐Sulfite
☒Other ephedra/Ma huang
☐Unknown

Product Label Available: ☒Yes ☐No ☐Unknown Product Sample Available: ☒Yes ☐No ☐Unknown
Suspect bottle discarded

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☐No

Life-Threatening: ☒Yes ☐No

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) Prolonged hospitalization

Mr. [redacted] is unresponsive. Information provided by Mrs. [redacted] & family.

Required intervention to prevent permanent impairment/damage: ☒Yes ☐No

Did the adverse reaction result in a congenital anomaly: ☐Yes ☒No

000010

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderly Place, Ste 200
Maitland, Florida 32751

Date: April 13, 1999

From: Investigator, [redacted]

To: Supervisory Investigator, HFR-SE2585

Subject: **Adverse Event Report**
[redacted]
CFSAN Project #13408
Re: Ripped Fuel Supplement

The subject assignment dated 3/19/99 was issued from CFSAN, Domestic Programs Branch, HFS-636. This assignment requested a follow-up investigation on an Adverse Event Report. This report detailed a consumer's reaction after ingestion of an ephedra alkaloid-containing product. The assignment requested the collection of medical records, product labeling and information to complete the Adverse Event Questionnaire form. Product labeling was previously submitted as documentary sample, DOC 46060. The initial interviews were reported under a separate memorandum dated 4/5/99. Copies of medical records were collected for two of the hospitals where the patient was treated. Copies of those records were attached and submitted with the 4/5/99 memorandum. The Adverse Event Questionnaire form and FDA complaint Form 2516 for complaint # [redacted] were also sent to HFS-636. The purpose of this memorandum is to provide the additional medical records collected and to provide an update on the investigational activities.

INVESTIGATION

As previously reported, Mr. [redacted] was first seen at [redacted] in [redacted]. On 2/24/99, Mr [redacted] was transferred to [redacted] at the request of his wife, Mrs. [redacted] and his parents, Mrs. [redacted] The [redacted] family reported that [redacted] continued to experience seizures while admitted at [redacted] and the family was concerned about the level of care that

TO: ARMS Monitor, DOEP, HFS-636

This memorandum records our investigational activities and provides the medical records for the third hospital. Attempts to interview the consulting and attending physicians were unsuccessful believed due to pending lawsuits. No additional follow-up activities are deemed necessary at this time.

Leon L. Law
Supervisory Investigator
[redacted]

Cc:FLA-DO
[redacted]

was provided to [redacted] He was transferred to [redacted] on 2/24/99. He was officially admitted to [redacted] on 2/25/99 according to Mr. [redacted] medical records. [redacted] medical personnel decided to induce a coma with pentobarbital to reduce the intracranial pressure. On 3/30/99, I reviewed the available medical record file at [redacted] nurse's station, for Mr. [redacted] A review of the consultation section of the medical chart found that various departmental staff and physicians recorded different interpretations at to the cause of [redacted] illness.

A toxicology consultation report (**Attachment #1**) dated 3/2/99 was available in the medical file. Mr. [redacted] attending neurologist, [redacted] M.D, requested this consultation. The handwritten report performed by a doctor of Pharmacy (name illegible) includes a statement that Mrs. [redacted] stated that [redacted] took Ripped Fuel "a handful at a time, several times per day". The recorded impression includes that the seizure condition was due to chronic ingestion (overdose) of ephedrine & caffeine combination. The report adds that toxicity can occur with 2-3x the therapeutic dose. The consultation suggested a comprehensive drug urine and drug screen with caffeine levels. No such report was found in the medical file. One drug screen report dated 2/25/99 was available and is attached in **Attachment #5.**

A consultation report (**Attachment #2**) dated 3/11/99 from an examination performed on 3/7/99 by [redacted] M.D. was available in the file. Dr. [redacted] is an internal medicine specialist who was requested to provide a consultation of Mr. [redacted] "hypermetabolic state" by attending neurologist, [redacted] M.D. [redacted] staff had found that they were unable to maintain appropriate levels of antiepilepsy medications and the seizures continued to occur with appropriate medication dosing. Dr. [redacted] report included statements that Mr. [redacted] had taken different medications including Ripped Fuel, Wastraw (anabolic steroid), Creatine, XTC and GHB. Dr. [redacted] assessment included that the patient had polysubstance drug abuse (**see Attachment #2 page #3**). The report does not record how Dr. [redacted] obtained this information. Another consultation, a handwritten report (undated) by the Critical Care department, signed by [redacted] medical student fourth year, also includes a notation of these additional drug and supplement products, **see Attachment #3.**

A consultation report was available in the file from [redacted] M.D., neurologist. Dr. [redacted] reported Mr [redacted] seizures were related to his consumption of the Ripped Fuel, **see Attachment #4**. The date of this examination is unknown. This report was dictated on 3/20/99.

Repeated attempts were made to interview Dr. [redacted] and Dr. [redacted] regarding their evaluation of Mr. [redacted] Their office staff did not permit any scheduled appointments and my calls have not been returned. The last visit to [redacted] was performed on 5/3/99. The [redacted] family has retained an attorney, [redacted] The attorney's office has been in contact with Mr. [redacted] physicians. I spoke with [redacted] from Mr. [redacted] office on 4/28/99. Ms. [redacted] was provided with the

complaint number and FOI request information. Ms. [redacted] stated that the hospitals have not allowed Mrs. [redacted] to collect copies of all the medical records.

Copies of the [redacted] medical records including additional consultation reports, patient history, lab reports, a portion of the physician progress notes were collected and are submitted as **Attachment #5**. On 4/9/99, Mr. [redacted] was transferred to [redacted] This hospital specializes in continued care, therapy and recovery management. No visit has been made to [redacted] and additional medical records were not requested. A discharge summary was not available from [redacted] A visit made to [redacted] on 5/3/99 found that the summary had not yet been provided from Dr. [redacted] according to the medical record staff. No discharge summary is provided. There were various articles concerning ephedrine in the medical records. Copies of these articles are provided as **Attachment #6**.

On 4/2/99, I again interviewed [redacted] at the [redacted] family home at [redacted] I asked Mrs. [redacted] to again clarify what medications and what quantities Mr. [redacted] had taken. Mrs. [redacted] responded consistently with the information provided during our initial interview on 3/29/99. She again confirmed she did not know how often her husband took the product. She stated he took two-three capsules at a time. Mrs. [redacted] denied that her husband was taking or had taken any other supplement or medication. I specifically questioned Mrs. [redacted] about the products reported in consultation reports. Mrs. [redacted] stated she was aware that distant family members had told some medical staff about [redacted] taking such products. She did not know that the information had been recorded in [redacted] medical record. Mrs. [redacted] stated that Mr. [redacted] biologic father, [redacted] and his brother, [redacted], and family had visited [redacted] at [redacted]. Mrs. [redacted] stated that she discovered that [redacted] uncle [redacted] had told the doctors that [redacted] had taken some other medications. She explained that the medical staff usually did not evaluate family member relationships and they must have recorded this misinformation from a conversation with the [redacted] family. She estimated that [redacted] had not seen his biologic father for two years. Mrs. [redacted] had previously phoned [redacted] concerning his statements. According to Mrs. [redacted] he admitted to hearing about the other drug products from another [redacted] family member and to not having any direct knowledge of [redacted] use of any supplements or medications.

No clarifications of the consultation report(s) information could be obtained due to lack of cooperation of medical personnel. The [redacted] are pursuing legal actions against the product manufacturer and at least one of the medical facilities. No further investigations or attempts for interviews are anticipated at this time.

ATTACHMENTS

1. Consultation report; Toxicology
2. Consultation report; Dr. [redacted]
3. Consultation report; Critical Care
4. Consultation report; Dr. [redacted]
5. [redacted] medical records
6. Ephedrine Articles

Shari J. Hamilton
Investigator
[redacted]